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# **MIXING AND POURING APPARATUS AND VESSEL THEREFOR**

## **Field**

5           The present invention relates generally to holding, mixing and pouring of vessels, and more particularly to mixing and pouring devices designed for vessels having removable screw caps, and the vessels themselves.

## **Background**

10           Currently, manual processes for working with chemicals in solution, isolation of components from solution, and the like involve time intensive operation of one (1) to 24 hours, including an overnight incubation period. Further, samples may need to be mixed, shaken, poured, agitated, and the like for certain time periods or a certain  
15   number of iterations.

          In many lab processes, a sample of some material which contains components to be isolated, mixed, or the like is typically placed in a sample vessel, and processes comprising the steps to be performed on the sample are performed on the vessel and its contents. Materials may be removed from the vessel, added to the vessel,  
20   transferred to another vessel, and the like.

          Typical lab procedures for working with samples include mixing and agitating the sample, adding material to the sample, removing material from the sample by pouring, and the like. These processes have traditionally been performed by hand. Such manual performance of tasks has been and continues to be labor  
25   intensive, requiring time consuming and repetitive tasks that occupy a technician, often to the exclusion of other tasks. The repetitive process steps of processes for working with chemicals, solutions, suspensions, and the like as described above require precision and attention to detail, and may often rely on the skill of the technician responsible for the isolation. Repetitive application of precise process  
30   steps lends itself to errors which may negatively affect the quality of the processes

performed. In the case of unique or limited samples, such errors may occur when dealing with samples that cannot be duplicated, or are irreplaceable.

Further, during many types of laboratory procedures, such as isolation of DNA, vessels are capped and recapped so that samples and reagents can be added,  
5 contents can be shaken or moved, and so forth. Many manufacturing processes, including processes for producing packaged foods, chemicals, medicines, and so forth also involve capping or uncapping of vessels, and the adding and removal of contents.

Typically, threaded vessels and caps are used. Oftentimes, however, it is  
10 difficult to start the cap threads squarely on the vessel threads, which can cause the cap to not be securely attached, leading to leakage of vessel contents. In some cases, it may be necessary to stop the entire operation to clean up the spill, leading to reduced productivity. During precise laboratory procedures, such as DNA or RNA isolation, such content loss can also cause contamination and cross-contamination of  
15 samples and the laboratory, such that the entire process needs to be restarted. Furthermore, if the vessel itself rotates as the cap is being secured, the vessel may remain uncapped or the cap may not be in the proper position, again leading to problems with loss of vessel contents. Vessel movement can also adversely affect fragile contents, such as coagulated DNA strands suspended in a liquid, which can be  
20 torn by viscous effects in the liquid.

### **Summary**

The present invention overcomes the problems of the prior art by providing a  
25 mixing and pouring apparatus for performing mixing and pouring tasks without requiring a user to perform the tasks, and vessels for use in such an apparatus.

The present invention further overcomes the problems of the prior art by providing a cap and vessel positioning system that securely locks a vessel in place and realigns a cap in essentially the identical position in relation to the vessel every

time the vessel is capped. In one embodiment, both the cap and vessel have flanges that are aligned when the cap is properly secured to the vessel.

In one embodiment, a mixing and pouring apparatus includes a base, and a locking arm support carried on the base. A locking arm is rotatably mounted within  
5 the locking arm support, and a drive mechanism is operatively coupled to the locking arm, the drive mechanism capable of rotating the locking arm.

In another embodiment, a vessel having a substantially square flange at the base of a series of external threads is disclosed. A cap having a substantially identical square flange and internal threads is threaded onto the vessel. In one  
10 embodiment, the vessel has multiple disjointed threads to provide an improved surface for starting the threads. In one embodiment, four-start threads are used. In this embodiment, the cap is adequately secured after minimal turning.

In another embodiment, the cap and positioning system further comprises a locking device for securing the vessel in a fixed position. The locking arm can be a  
15 pair of partitions on a lab rack, or a locking pocket in a storage rack or the shaking and pouring device as described above.

In another embodiment, a method for positioning and repositioning a vessel and cap in a substantially identical location is disclosed. The method further includes securing the vessel or a vessel and cap assembly in a suitable locking arm  
20 for storage, transport, shaking, and so forth.

Other embodiments are described and claimed.

### **Brief Description of the Drawings**

25 Fig. 1 is a perspective view of one embodiment of an apparatus for mixing and pouring;

Fig. 2 is a rear elevation view of the embodiment of Fig. 1;

Fig. 3 is a partial side view of a trough embodiment of the present invention pouring to waste;

Fig. 4 is a partial side view of the trough embodiment of Fig. 3 pouring to save;

Fig. 5 is a front elevation view of a trough embodiment of the present invention;

5 Fig. 6 is a front elevation view of an embodiment of a registration mechanism of the present invention in a home position;

Fig. 7 is a front elevation view of the embodiment of Fig. 6 with the registration mechanism displaced from its home position;

Fig. 8 is a side elevation view of the embodiment of Fig. 6;

10 Fig. 9 is a block diagram view of a control embodiment of the present invention;

Fig. 10 is a flow chart diagram of a method embodiment of the present invention;

15 Fig. 11 is an exploded perspective view of a cap and vessel in one embodiment of the present invention;

Fig. 11A is a roll-out view of multiple disjointed threads in one embodiment of the present invention;

Fig. 12A is a top view of a cap in one embodiment of the present invention;

20 Fig. 12B is a cross-sectional view of a cap in one embodiment of the present invention;

Fig. 12C is a bottom view of a cap in one embodiment of the present invention;

Fig. 13A is a top view of a vessel in one embodiment of the present invention;

25 Fig. 13B is a cross-sectional view of a vessel in one embodiment of the present invention;

Fig. 14 is a cut-away perspective view of vessels in place on a lab rack in one embodiment of the present invention;

30 Fig. 15 is a cut-away perspective view of vessels and caps in a storage rack in one embodiment of the present invention; and

Fig. 16 is a cut-away perspective view of vessels with caps in a shaking and pouring device in one embodiment of the present invention.

### **Description of Embodiments**

5

In the following detailed description of embodiments, reference is made to the accompanying drawings which form a part hereof, and in which are shown by way of illustration specific embodiments in which the invention may be practiced. In the drawings, like numerals describe substantially similar components throughout the several views. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other  
10 embodiments may be utilized and logical, structural, electrical, and other changes may be made without departing from the scope of the present invention.

Figure 1 shows one embodiment of a mixing and pouring apparatus 100.  
15 Mixing and pouring apparatus 100 comprises a base 102, a locking arm support 104, rotatable locking arm 106, drive mechanism 108, and motor 130 (shown best in Fig. 2). Mixing and pouring apparatus 100 is suitable for use with a vessel and cap structure 110 such as vessel 112 and cap 114 shown in greater detail in Figures 11, 11A, 12A, 12B, 12C, 13A, and 13B and described below.

20 Base 102 serves as a support for the remaining components of the mixing and pouring apparatus 100. Base 102 includes on one embodiment guide pin openings 132 capable of receiving a supplemental vessel and cap cradle for use in a pouring operation to be described later. Locking arm support 104 includes openings for receiving a support or supports for the locking arm 106 at its ends 144 and 146.  
25 Shaft 134 of locking arm support 104 is fixedly connected to drive mechanism 108 and locking arm 106 for effecting motion of locking arm 106 in response to operation of the drive mechanism 108.

Locking arm 106 is rotatable about the longitudinal axis of the shaft 134, and is rotated upon actuation of the drive mechanism 108 to effect the rotation or other  
30 motion of the locking arm 106 initiated by the drive mechanism 108. As will be

described in greater detail below, locking arm 106 is capable of holding and retaining vessels such as vessel 112 within one of a plurality of vessel openings 140 in the top of the locking arm 106. As will be described below, each of the vessel openings 140 in the locking arm 106 is surrounded by a locking pocket 142 which is shaped and  
5 sized in one embodiment to match a flange such as flange 118 of a vessel such as vessel 112 to secure the vessel against rotation in the locking pocket 142 and opening 140.

The locking arm 106 further comprises in one embodiment vacuum locking ports 144 which serve to secure a vessel such as vessel 112 into the locking arm 106  
10 so that the locking arm with the vessel therein may be rotated, tipped, inverted, or the like, without the vessel falling out of the locking arm. In this embodiment, each of the locking ports 144 comprises a locking opening 146 (also shown in Fig. 16) having at its edge an O-ring 148 to seal the opening 146 when a vessel such as vessel 112 is placed in the opening 146 and a vacuum or partial vacuum is drawn below the  
15 port 144.

A vacuum or partial vacuum is drawn below the port 144 which holds the vessel 112 against the O-ring 148 within the port opening 146, thereby retaining the vessel 112 within the port 144 and within the locking arm 106. Once the vessel 112 is secured within the port 144, the locking arm may be rotated, tipped, or the like  
20 without the vessel 112 being separated from the locking arm. If a cap such as cap 114 is on the vessel 112, then any motion of the locking arm 106 will result in an agitation, nixing, or shaking of the contents of the vessel 112. If the cap 114 is removed from the vessel 112, then the rotation of the locking arm 106 will result in a pouring of contents from the vessel 112.

In one embodiment, a vacuum line 150 is connected to an external vacuum pump in one embodiment. It should be understood that an internal vacuum pump could also be used. It is sufficient that some vacuum pump be connected to the ports 144 to draw a partial vacuum below the vessel tip 117. In cutaway in Fig. 1, one embodiment of a connection of a vacuum line 150 to several ports 144 is shown. In  
25  
30 this embodiment, the vacuum line 150 is connected from an external vacuum pump

to the locking arm 106. Internal to the locking arm, the vacuum line 150 is connected to each of the ports 144 so as to draw a partial vacuum at each port when the vacuum pump is turned on.

The partial vacuum is also applied when the contents of the vessel 112 are being poured out so that the vessel 112 will not fall out of the mixing and pouring station 100 as it is being tipped. In this way, the vessel 116 can be rotated beyond a horizontal position without slipping out, and its contents emptied out completely, or sufficiently to remove excess material while leaving desirable material in the vessel 112.

In other embodiments, other apparatuses for holding vessels such as vessel 112 within the locking arm 106 include by way of example only and not by way of limitation clamps, threads, clips, pins, and the like. It is sufficient that the vessels be held in the locking arm 112 so that if inverted, the vessels will not fall out of the locking arm 112.

As is best seen in Figs. 1 and 2, the drive mechanism 108 comprises in one embodiment a pair of gears, drive gear 152 and free gear 154. Drive gear 152 is operatively coupled to shaft 156 of motor mechanism 130, and therefore rotates when shaft 156 rotates. Free gear 154 is fixedly coupled to shaft 134, and rotates therewith. As has been mentioned, shaft 134 is fixedly coupled to locking arm 106. Therefore, when free gear 154 rotates, shaft 134 and locking arm 106 also rotate. A belt 158 is seated over gears 152 and 154. In one embodiment, gears 152 and 154 are notched, and belt 158 is notched, so that the notches of belt 158 fit the notches of gears 152 and 154. In this embodiment, rotation of the drive gear 152 directly corresponds to rotation of the free gear 154 at a known ratio. The notches of the gears 152 and 154, and of the belt 158, eliminate to a large extent any potential slippage of the belt 158 on the gears. When the motor 130 operates, the shaft 156 rotates, driving the drive gear 152, moving the belt 158 to rotate the free gear 154 and consequently the shaft 134 and the locking arm 106.

The motor 130 is in one embodiment controlled externally by a computer control. Computer control signals are sent to the motor 130 along line 129. Such a



computer control allows the choice by a user of the operation of the motor, and therefore the motion of the locking arm through the operation of the drive mechanism 108. In this embodiment, a user can program a single operation of the locking arm, or multiple operations of the locking arm. For example, if it is desired to mix the contents of a vessel retained within the locking arm, the user may choose rotation of the locking arm in complete 360 degree rotations about the longitudinal axis of the shaft. The speed of rotation is adjusted or set by the user, and the known ratio of the drive gear size to the free gear size allows the computer to program the motor to drive shaft 156 at the appropriate rotational speed to supply the desired rotational speed of the locking arm 106.

Motor 130 is in one embodiment a so-called smart motor. The motor 130 in this embodiment includes a processor and memory (Fig. 9) which are capable of executing and storing a series of commands for operation of the apparatus 100 without further input from an external control. The commands are in one embodiment downloaded to the memory over computer control line 129, and are executed in the process without further input from the external computer control. In this embodiment, an entire sequence of steps may be programmed into the motor 130 for execution at a later time, such as when the apparatus 100 is unattended, or when the steps of the process are lengthy and it is not necessary for a user such as a scientist or technician to be present to oversee each step or the full process.

A computer control system capable of operating the apparatus 100 is disclosed in co-owned U.S. Application Serial Nos. 09/255,146, entitled COMPUTER IMPLEMENTED DNA ISOLATION METHOD, filed February 22, 1999, and 09/361,829, entitled COMPUTER IMPLEMENTED NUCLEIC ACID ISOLATION METHOD AND APPARATUS, filed July 27, 1999, which are herein incorporated by reference in their entirety.

Motor 130 and drive mechanism 108 in one embodiment have a registration mechanism to ensure that the locking arm begins its operational processes from the same position each time the apparatus 100 is started. Such registration mechanism is shown in greater detail in Figs. 2, 6, and 7. A registration disk 137 is fixedly

attached to shaft 134, so that registration disk 137 will rotate when shaft 134 rotates as described above. Registration disk 137 has therein along its circumference a registration slot 139 extending inward from the outer edge toward shaft 134. In the position shown in Fig. 6, the registration slot is aligned with optocoupler 138 when  
5 the locking arm 106 is substantially vertical with respect to the plane 131 of the base 102 of apparatus 100.

Optocoupler 138 has an optical transmitter 133 each electrically connected to the motor 130. Transmitter 133 emits a light signal. When slot 139 is between the transmitter 133 and optical receiver 135, receiver 135 receives the light signal from  
10 transmitter 133, indicating that the registration disk 137 is in its "home" position, that is, the locking arm 106 is substantially vertical with respect to plane 131. If no signal is received by receiver 135, then the registration disk 137 and hence the locking arm 106 and any vessels 112 retained therein are not substantially vertical. The motor 130, upon startup, will rotate the shaft 156, and therefore operated drive  
15 mechanism 108, to bring the registration disk 137 back to its home position before initiating any mixing or pouring operations.

In the position shown in Fig. 7, the registration disk 137 has rotated through an angle  $\alpha$ , as has the locking arm 106. If the locking arm is rotated away from the home position shown in Fig. 6 before initiation of a process step, the optocoupler  
20 does not make a connection and the motor rotates the shaft 156 until the optocoupler makes a connection between its transmitter 133 and receiver 135.

It should be understood that other registration mechanisms may be used without departing from the scope of the invention. For example, but not by way of limitation, such registration could be accomplished by manual rotation and  
25 alignment, through the known gear ratio of free gear 154 to drive gear 152, or the like.

Alternatively, the user may choose to invert the vessels retained within the locking arm 106. This action may be repeated multiple times. It should be understood that any number of sequences of rotational motion may be programmed

into a computer control as described above, or may be initiated by the user by utilizing the computer control.

Another action which may be desired by a user is a pouring action. In many laboratory processes, materials must be poured from the vessels. The material removed from the vessel may be waste material, or it may be material to be saved. Such pouring operations are referred to herein as “pour to waste” and “pour to save” respectively.

The locking arm support 104 of apparatus 100 in one embodiment includes a waste trough 160 (Figs. 1, 3, and 5) having a center drain 162 connected to a drain hose 164. Waste trough 160 receives “pour to waste” material poured from a vessel 112 retained within the locking arm 106 when the vessel 112 has its cap 114 removed and the locking arm 106 rotates toward the back 168 of apparatus 100. As is best seen in Fig. 3, when locking arm 106 is rotated toward back 168 of apparatus 100 while a capless vessel 112 is retained within locking arm 106, any waste fluid from vessel 112 is poured into trough 160 to drain out drain 162 and drain hose 164.

In one embodiment, trough 160 has bottom surfaces 166 which are angled downward and inward from edges 170 and 172 of trough 160 so that drain 162 is located at the physical lowest point of trough 160 when trough 160 is substantially vertical, to facilitate proper draining of waste material from trough 160. It should be understood that any drain configuration allowing the trough 160 to drain would suffice, and the invention is not limited to a center drain.

Referring now also to Fig. 4, one embodiment of a pour to save configuration is shown in greater detail. In the pour to save operation, when a capless vessel 112 is retained within locking arm 106, and locking arm 106 is rotated toward the front 174 of apparatus 100, any fluid from the vessel 112 is poured from the vessel 112 into another vessel 113 held in a supplemental vessel cradle 107 which is similar in shape and size to locking arm 106, but which does not contain the vacuum ports or vacuum connections of locking arm 106. Cradle 107 has a plurality of guide pins 176 which engage guide pin openings 132 in base 102 of apparatus 100 so as to position

supplemental cradle 107 to receive vessels such as vessel 113 capable of retaining fluid poured from vessels 112 retained within locking arm 106.

As they are used herein, the terminology top, bottom, and sides are referenced according to the views presented. It should be understood, however, that the terms  
5 are used only for purposes of description, and are not intended to be used as limitations. Orientation may change without departing from the scope of the invention.

Fig. 9 shows a block diagram of an embodiment 900 of an apparatus such as apparatus 100 and its connects to an external vacuum pump 902 and computer  
10 control 904. In one embodiment, motor 130 includes processor 906 and memory 908, whose functions have been described above.

One embodiment of the cap and vessel assembly 110 is shown in Fig. 11. In this embodiment, the cap and vessel assembly 110 comprises a vessel 112 and a cap 114. The vessel 112 comprises a vessel body (or skirt) 116 contiguous with a vessel  
15 flange 118. The vessel body 116 has individual or “disjointed” external threads 1120a, 1120b, 1120c and 1120d (hereinafter “1120a-1120d”) visible on one side of an upper portion of the vessel body 116 above the vessel flange 118. There can be any suitable distance or “groove” between the external threads 1120a-1120d. In one embodiment, the distance between threads is about two to three times the thickness  
20 of each thread.

The vessel body 116 can be any size and shape depending on the application. It should be understood that for different sizes and shapes of vessels, different locking openings and ports are contemplated, and are within the scope of the invention. In one embodiment, the vessel body 116 is a cylindrically-shaped tube as  
25 shown in Fig. 11. Such a tube can have a tapered bottom as shown in Fig. 11, or can have a flat or rounded bottom as desired. This type of tube is typically used in a laboratory as a test tube into which small amounts of samples and reagents are placed.

In one embodiment, the vessel 112 is a tube that holds about 50 ml of fluid  
30 material and has a length of about 11.4 cm (about 4.5 in), an inner diameter of about

2.8 to three (3) cm (about 1.1 to 1.2 in) with a wall thickness of about 0.1 cm (about 0.4 in). The tapered bottom can be designed in any suitable manner. In one embodiment, the tapered portion has an angle 1122 of about 54 degrees starting about 1.5 cm (about 0.6 in) up from the bottom in a vessel 112 having an overall length of about 11.4 cm.

The disjointed external threads 1120a-1120d, can have any known type of profile or form, such as American Standard, square, Acme, and so forth. In another embodiment, conventional joined single or multiple threads are used. In the embodiment shown in Fig. 11, quadruple or “four-start” external disjointed threads are used. In this way the cap 114 can be securely fastened to the vessel 112 with a minimum of turning. The threads can be present along any suitable length of the vessel 112 and in one embodiment, extend to just above the vessel flange 118. In one embodiment, the external threads 1120a-1120d cover about the upper 1.2 cm (0.48 in) of a vessel having an overall length of about 11.4 cm.

In a disjointed thread configuration, each individual thread typically extends around the circumference of a vessel body in proportion to the number of disjoint threads in the configuration. In a triple or “three-start” configuration, there are three separate threads, each of which start and stop at approximately 120 degree intervals. In a “four-start” thread configuration, as shown in Fig. 11, there are four separate external threads 1120a-1120d. Each external thread 1120a-1120d starts and stops at approximately 90 degree intervals in relation to the adjacent thread, and each thread extends approximately 180 degrees around the top of the vessel body 116.

In a roll-out view of the external threads 1120a-1120d shown in Fig. 11A, it can be seen that each thread starts at the about the same distance down from the top of the vessel body 116. As such, a corresponding cap with four matching disjointed threads (which have the same configuration as shown in Fig. 11A) will initially rest on all four external threads 1120a-1120d on the vessel body 116 no matter where it is placed on the vessel 112.

In the embodiment shown in Figs. 11 and 11A, the threads are male threads that are all at a slight angle in relation to horizontal, although the invention is not so

limited. Angling the threads in this way, however, allows them to be molded more easily. Further, the slight angle provides an upwardly facing relief face on the lower side of the external threads 1120a-1120d as is known in the art. In one embodiment, the angle is about ten (10) to 25 degrees. In another embodiment, the angle is about  
5 20 to 22 degrees.

Referring again to Fig. 11, the vessel flange 118 can be any suitable size and shape provided it can serve to hold the vessel 112 in a fixed position on a suitable locking arm, such as the locking arm 106 or supplemental cradle 107 of mixing and pouring device 100 discussed above. In one embodiment, the vessel flange 118 is  
10 compatible with the corresponding cap flange 128 discussed in more detail below. In one embodiment, the vessel flange 118 is substantially square, triangular, round or rectangular shaped. In the embodiment shown in Fig. 11, the vessel flange 118 is substantially square shaped with each corner is angled, although the invention is not so limited. However, by removing the sharp edges at each corner, added comfort is  
15 provided for the person handling the vessels 112 and caps 114.

In one embodiment, the vessel flange 118 surrounds the entire circumference of the vessel body 116. The vessel flange 118 can be any suitable size in relation to the vessel body 116. In one embodiment, the combined diameter of the vessel body 116 and vessel flange 118 is about one (1) to 15% greater than the outer diameter of  
20 the vessel body 116 along all sides. In another embodiment, the vessel flange 118 extends beyond the vessel body 116 only in the corner areas of the vessel flange 118. In another embodiment, the vessel flange 118 does not surround the entire circumference of the vessel body 116, and is present only on certain portions of the vessel body 116, such as on two opposing sides or at three or more locations, such as  
25 in a spoke arrangement. In one embodiment, the vessel flange is about 0.02 to 0.6 cm (about 0.008 to 0.24 in) thick.

The cap 114 comprises a cap body (or skirt) 126 and cap flange 128, which is integral with the cap body 126. The cap body 126 shown in Fig. 11 is substantially circular in shape and has a circular internal ridge (shown in Fig. 12B) around which  
30 the top of the vessel body 116 sets. The cap body 126 further has internal threads

1130a, 1130b, 1130c and 1130d (hereinafter "1130a-1130d") as shown. The internal threads 1130a-1130d can be any conventional type of threads, but in one embodiment are also individual or disjointed threads substantially identical to the external threads 1120a-1120d on the vessel body 116. In one embodiment, the  
5 internal threads 1130a-1130d are also male threads. In another embodiment, the internal threads 1130a-1130d are female threads. Molding female threads in this manner is more difficult, however, because the cap body 126 needs to be thickened to compensate for loss of wall thickness in the area of the threads. The end result is a larger and thicker cap 114.

10 The internal threads 1130a-1130d can be substantially horizontal or at any suitable relief angle, which can be a minimum relief angle as shown in Fig. 11. As noted above, angling the internal threads 1130a-1130d in this manner allows them to be molded more easily as discussed above, although the angle should not be so steep as to cause the internal threads 1130a-1130d to "jump" the external threads 1120a-  
15 1120d on the vessel body 116 when being screwed on. Further, angling the threads in this manner provides a downwardly facing pressure face on the upper side of the internal threads 1130a-1130d as is known in the art. In one embodiment, the angle is about ten (10) to 25 degrees. In another embodiment, the angle is about 20 to 22 degrees.

20 The dimensions and shape of the cap flange 128 are substantially identical to the corresponding vessel flange 118. In one embodiment, the cap flange 120 is substantially square and is nearly flush with the outer diameter of the cap body 126 on four sides, extending outwardly from the cap body 126 only in the four corner areas as shown in Fig. 11.

25 The vessel 112 and cap 114 can be made from any suitable material. In one embodiment, the vessel 112 and cap 114 are made from an inert material which does not react with the contents of the vessel. In a particular embodiment, the vessel 112 and cap 114 are injection molded with polypropylene. Each component further has a small draft in order to remove the die as is known in the art. Additionally, the

parting line flash for each can be held to any suitable amount, such as less than about 0.003 in witness, as is known in the art.

In one embodiment, the male threads in both the cap and vessel are made with an unscrewing core or die which leaves strong and substantial threads to provide a tight lock-up with mating threads. This is in contrast to internal cap threads made using a steel core pin, which are typically very rounded so the cap can be easily snapped off the molding core pin. In one embodiment, the threading cores in the die for the caps and vessels have virtually identical phasing relationships such that the internal (cap) threads 1130a-1130d produced in the die are virtually identical and in phase with the external (vessel) threads 1120a-1120d, all of which are also virtually identical. Further, by molding in virtually identical anti-rotating devices, i.e., vessel flanges 118 and cap flanges 128, on both the vessel 112 and cap 114 at the same point in relation to the threads, all of the internal threads 1130a-1130d in every cap 114 locate virtually to the same depth as every other cap 114.

The cap body 126 and vessel body 116 can further have any suitable texture. In one embodiment, some or all of the cap body 126 and/or vessel body 116 has a knurled or ridged texture comprised of a series of vertical lines. Typically such a knurled surface aids in gripping and serves as a type of “anti-rotation” device. This type of surface may be useful in embodiments in which there are no other anti-rotation devices, i.e., the cap flange 128 and/or vessel flange 118.

In operation, the cap body 126 is placed over the vessel body 116 and the cap 114 can be given a turn sufficient to provide sealing of the contents inside the vessel 112. With a four-start thread configuration for the external threads of the vessel 112 as described above, it is possible to obtain an adequate seal with less than a 1/4 or 90 degree turn of the cap body 126 in relation to the vessel body 116. In another embodiment, the cap body 126 is turned any amount up to 360 degrees. The amount of rotation needed to secure the cap 114 depends on where the cap 114 is placed initially. In any of these embodiments, the vessel 112 is sealed when the edges of the flanges (118 and 128) are aligned. Specifically, in one embodiment, the cap 114 comes to an abrupt stop at this point and further turning does nothing to change the



relationship between the cap 114 and vessel 112. This is due to the particular design of the internal and external threads 1130a-1130d and 1120a-1120d, respectively, including the profile shape, angle, and so forth. The amount of rotation required to remove the cap 114 from the vessel 112 can be designed to be any suitable amount.

5 In one embodiment, the assembly 110 is designed to require a 180 degree rotation for removal. Such rotation amount depends on the ramp angle of the threads, space between the top of cap 114 and beginning of the threads, and so forth. In this way, a suitably designed automated device, such as a cap rotator, discussed below, can be used to secure and remove the caps 114 by rotating the cap (114) 180  
10 degrees in either direction. In this embodiment, the assembly 110 can be designed to require up to a 180 degree rotation for removal even if less than a 180 degree rotation is needed to secure the cap 114 to the vessel 112. In one exemplary embodiment, the ramp angle of the internal threads 1130a-1130d is about 21 degrees and the threads are spaced down about 0.44 cm (0.175 in) from the top of a cap 114 having an inner  
15 diameter of about 2.7 cm (1.05 in) and an outer diameter of about 2.8 cm (1.12 in).

With use of multiple individual threads, the internal threads 1130a-1130d of the cap 114 load on multiple and separate thread surfaces (1120a-1120d) on the vessel body 116, rather than on only one, providing a more stable positioning system. Although multiple threads provide enhanced stability as compared with a single  
20 thread, some tipping can still occur with double and triple thread configurations. With use of the four-start threads for the external threads of the vessel body 116, there are four individual threads 1120a-1120d onto which the four internal threads 1130a-1130d of the cap 114 are in communication with initially as shown above in Fig. 11A, providing a flat plane, thus preventing tipping. In this way, the cap 114  
25 can be taken on and off relatively quickly.

Additionally, use of the cap flange 128 not only helps with correctly positioning and repositioning the cap body 126 on the vessel body 116, it also serves as a strengthening device. Specifically, with the cap flange 128 present, the cap body 126 can not expand or bend if excess torque is applied. Similarly, the vessel flange  
30 118 prevents the vessel body 116 from caving in if the cap body 126 is secured to the

external threads 1120a-1120d with excess torque. Generally, the use of torque is not required with this type of thread arrangement, and complete sealing can be obtained with minimal turning, as noted above.

Fig. 12A is a top view of the cap 114, showing the cap flange 128 and cap body 126 as described above. Fig. 12B is a cross-sectional view of the cap 114 showing the cap body 126 and internal threads 130. As noted above there is also an internal ridge 1210 around which the top of the vessel body fits. Fig. 12C is a bottom view of the cap 114 showing the cap flange 128, as well as the inner and outer diameters of the cap body 126 and the internal ridge 1210.

Fig. 13A is a top view of the vessel 112 showing the vessel flange 118 and vessel body 116. The wall 1310 of the vessel body 116 can also be seen in this view. Fig. 13B is a cross-section of the vessel 112 showing the wall 1310, the vessel flange 118 and the external threads 1120a-1120d as described above.

The assembly 110 can be placed in any number of devices that serve to hold the assembly 110 in position and further aid in positioning the cap 114 to the vessel 112. Fig. 14 shows one embodiment of a lab rack 1410 which has been modified to have partitions 1412 between rows of holes 1414. Any suitably sized lab rack 1410 can be used. In one embodiment, there are four rows of holes 1414, each row having eight (8) holes 1414 through which 32 vessels 112 can be placed. In this embodiment, the partitions 1412 run the entire length of the lab rack 1410. The partitions 1412 are spaced such that two opposing sides of each vessel flange 118 are in contact with adjacent partitions 1412 when in place on the rack 1410 and properly positioned. In this way, the vessel 112 is held securely in place so that samples or reagents can be added, the vessel 112 can be capped, and so forth.

In one embodiment, a lab operator loads a portion of the rack 1410, such as about half, with samples. If a bar code is present on the vessel 112, that can be scanned into a suitable scanning device at this time. When the operator is ready to seal the contents of a vessel 112, the operator manually places a cap 114 (which can also have a bar code) onto a vessel 112, turning the cap 114 until the cap flange 126 is aligned with the vessel flange 118. As with the placement of the vessels 112, the

presence of the partitions 1412 on either side of each row insures that the caps 114 will be placed in the correct position. Specifically, if the vessel flanges 118 and cap flanges 128 are not in alignment, the vessels 112 and caps 114 will not fit in between the partitions 1412. Further, as discussed above, the thread design and seating tolerances cause the cap 114 to come to an abrupt stop when it is in proper alignment, so that this proper alignment is easily achieved. Therefore, with substantially square cap and vessel flanges, 128 and 118, respectively, the cap 114 and vessel 112 can be dropped into position in four different ways, i.e., along any of the four edges of the flanges 118 and 128.

Fig. 15 shows a shuttle device 1510 which is used to store the cap 114 and vessel 116. The cap 114 and vessel 112 can be stored in the shuttle device 1510 when not in use, or for transport during any type of procedure. Such procedure can be any type of manual or automated procedure. As Fig. 15 shows, the shuttle device 1510 contains pairs of identical holes for storing a vessel 112 and its corresponding cap 114. The shuttle device 1510 comprises the same type of holes 140, each with a step or locking pocket 142 as the mixing and pouring device 100 discussed in Fig. 1. The locking pocket 142 is designed to be the same size and depth as the flanges, i.e., cap flange 128 and vessel flange 118. The shuttle device 1510 can contain any number of holes 140 as desired for a particular application. In one embodiment, there are four (4) pairs of holes 140 to support four pairs of vessels and caps.

When capping the vessel 112, the cap 114 can be picked up, placed on the vessel 112 and rotated the desired amount, such as 90, 180, 270 or 360 degrees. In one embodiment, the cap 114 is rotated approximately 180 degrees clockwise in relation to the vessel 112. When the cap 114 is removed from the vessel 112, it is rotated the same amount in reverse and placed back in its original hole. In one embodiment, the cap 114 is screwed onto the vessel 112 with a  $\frac{1}{2}$  or 180 degree rotation in one direction and unscrewed with a  $\frac{1}{2}$  or 180 degree rotation in the opposite direction.

In one embodiment, the caps 114 are picked up simultaneously and automatically by a series of cap rotators 1516, placed on the vessel 116 and rotated

180 degrees. Each cap rotator 1516 comprises a cap rotator body 1518 and two blades or fingers 1520. The blades 1520 can be made from any suitable material, such as replaceable tool steel. In one embodiment, the blades 1520 are secured to the rotator cap body 1518 with a suitable connector 1522. Each cap rotator 1516 further  
5 has an internal suction cup (not shown) to hold the cap 114 firmly in place as it is being transported or rotated. Any number of cap rotators 1516 can be used so that multiple caps 114 can be picked up and moved simultaneously.

An embodiment of the vessel sealing method 1000 described herein is shown in Fig. 10. Method 1000 comprises placing a threaded cap having a cap flange on a  
10 threaded vessel having a vessel flange in block 1002, and securing the threaded cap to the threaded vessel a first time by rotating the threaded cap in one direction, the threaded cap secured to the threaded vessel when the cap flange and vessel flange are aligned in block 1004.

In the embodiment shown in Fig. 15, each of the holes 140 further have  
15 recesses 1524 on opposing sides into which the opposing blades 1520 on the cap rotator 516 slide to pick up the cap 114 in order to move it out of the locking pocket 142. The process is completed in reverse when it is desired to remove the cap 114. In other words, the cap 114 is rotated 180 degrees in the reverse direction and returned to the locking pocket 142 in the same position it began. The screwing and  
20 unscrewing of the cap 114 and placement in the locking pocket 142 can also be completed manually. In one embodiment, bar codes are used to identify the vessel 112 and cap 114 so that the same cap 114 is always used with the same vessel 112. This helps to ensure that there is no contamination or cross-contamination, although in most embodiments all of the vessels 112 and caps 114 are made with the same die  
25 so that the caps and vessels are interchangeable.

The shuttle device 1510 or the cap rotators 1520 can also be used to move the vessels 112 and caps 114 to any location desired in the process, such as underneath reagent dispensing devices, to centrifuging stations and into alignment with subsequent lab racks 1410 (shown in Fig. 14).

The shuttle device 1510 can also transport vessel and cap assemblies 110 to the mixing and pouring station 100 described above, as shown in Fig. 16. The holes 140 with opposing recesses 1524 as well as the locking pocket 142 are the same as shown in previous figures. By locking the flanges, 128 and 118, in place in this way, 5 the assembly 110 does not come loose and start to reposition itself during a shaking or pouring step. Any suitable number of assemblies 110 can be placed in the mixing and pouring station 100. In one embodiment, eight assemblies 110 are placed in this device. The assemblies 110 can be moved to this location manually or automatically, such as with the cap rotator 1516 as shown. In the embodiment 10 shown in Fig. 16, the vacuum port 144 serves to further secure the vessel 116 in place, particularly when the cap 114 is being rotated on or off.

The various holding devices shown in Figs. 1, 14, 15 and 16 can be used individually or in combination in any type of automated or manual laboratory or manufacturing procedure as described above.

15 The mixing and pouring apparatus 100 allows a user to more closely control the operations of mixing, agitating, and pouring. The apparatus 100 is precisely controlled by the motor 130 and external computer control, so that it is capable of performing any number of programmed tasks.

Furthermore, the cap and vessel flanges of the present invention provide 20 means to cap and recap a vessel without losing track of where threads are located on the vessel, such that the cap is resecured to the vessel in substantially the identical location and manner each and every time. Rotation of the cap then engages the two sets of threads evenly and consistently. Once the flanges are oriented in the same direction, the vessel is tightly sealed. Proper alignment also ensures that the vessel is 25 locked into position for transport, shaking, and so forth. Through use of multiple disjointed threads on the vessel, the cap and vessel positioning system of the present invention has the added advantage of providing a tight seal with only a minimum amount of turning.

Although specific embodiments have been illustrated and described herein, it 30 will be appreciated by those of ordinary skill in the art that any arrangement which is

calculated to achieve the same purpose may be substituted for the specific embodiments shown. This application is intended to cover any adaptations or variations of the invention. It is intended that this invention be limited only by the following claims, and the full scope of equivalents thereof.

Patent Attorney

What is claimed is:

1. A cap and vessel positioning system comprising:  
a threaded cap having a cap flange; and  
5 a threaded vessel having a vessel flange, wherein the threaded cap is secured to the threaded vessel when the cap flange and vessel flange are aligned.
2. The positioning system of claim 1 wherein the threaded vessel and thread cap have multiple disjointed threads.
- 10 3. The positioning system of claim 2 wherein the threaded vessel and threaded cap each have four disjointed threads extending about 180 degrees around the circumference of the threaded vessel, further wherein each thread starts in a location about 90 degrees away from an adjacent thread.
- 15 4. The positioning system of claim 1 wherein the cap flange and vessel flange each have four sides of about the same length.
5. The positioning system of claim 4 wherein the cap flange and the vessel  
20 flange are substantially square.
6. The positioning system of claim 4 wherein the threaded vessel and threaded cap each have four disjointed threads extending about 180 degrees around the circumference of the threaded vessel, further wherein each thread starts in a location  
25 at the midpoint of one of the vessel flange sides, and about 90 degrees away from an adjacent thread.
7. The positioning system of claim 4 wherein the threaded cap is secured to the threaded vessel a first time after being rotated in one direction approximately 180  
30 degrees.

8. The positioning system of claim 4 wherein the threaded cap is secured to the threaded vessel after being rotated in one direction about 360 degrees or less.

9. The positioning system of claim 7 wherein the threaded cap is removed from the threaded vessel after being rotated in an opposing direction 180 degrees, further wherein the threaded cap is resecured to the threaded vessel in substantially the identical position as the first time.

10. The positioning system of claim 9 wherein the threaded cap is lifted from and returned to a locking pocket when not in use on the vessel.

11. The position system of claim 10 wherein the threaded cap is lifted and returned to the locking pocket with a cap rotator.

12. The positioning system of claim 1 wherein the threaded cap and threaded vessel are injection molded using polypropylene.

13. A cap and vessel positioning system comprising:  
a locking arm having an opening with a locking device; and  
a threaded vessel having a vessel flange, the threaded vessel securable in the locking device.

14. The positioning system of claim 13 wherein the locking device is a pair of partitions or a locking pocket.

15. The positioning system of claim 13 further comprising a threaded cap having a cap flange, the threaded cap securable to the threaded vessel.

16. The positioning system of claim 13 further comprising a cap rotator with a suction cup.



17. The positioning system of claim 16 wherein the cap rotator has blades on opposing sides, further wherein the cap is held between the blades.

18. A method for sealing a vessel, comprising the steps of:

5 placing a threaded cap having a cap flange on a threaded vessel having a vessel flange; and

securing the threaded cap to the threaded vessel a first time by rotating the threaded cap in one direction, the threaded cap secured to the threaded vessel when the cap flange and vessel flange are aligned.

10

19. The method of claim 18 further comprising the steps of:

removing the threaded cap from the threaded vessel by rotating the threaded cap in an opposing direction; and

15 resecuring the threaded cap to the threaded vessel in substantially the identical position as the first time.

20. The method of claim 19 wherein the threaded vessel and threaded cap each have multiple disjointed threads.

20 21. The method of claim 20 wherein the threaded cap is secured to the threaded vessel the first time after being rotated in one direction less than about 360 degrees.

22. The method of claim 20 wherein the steps of placing, securing, removing and resecuring are automated, further wherein the cap is secured or resecured to the  
25 vessel by rotating the cap approximately 180 degrees in one direction, the cap removed from the vessel by rotating the cap approximately 180 degrees in the opposite direction.

23. A mixing and pouring apparatus, comprising:  
30 a base;

a locking arm support carried on the base;  
a locking arm rotatably mounted within the locking arm support; and  
a drive mechanism operatively coupled to the locking arm, the drive  
mechanism capable of rotating the locking arm.

5

24. The apparatus of claim 23, and further comprising a motor operatively  
connected to the drive mechanism, the motor effecting operation of the drive  
mechanism to rotate the locking arm.

10 25. The apparatus of claim 23, wherein the locking arm further comprises a  
plurality of vessel openings and a matching plurality of vacuum ports, each of the  
vessel openings sized to accommodate a vessel, and each of the locking ports capable  
of retaining the vessel in the locking arm.

15 26. The apparatus of claim 25, wherein the locking arm further comprises a  
plurality of locking pockets, one locking pocket of the plurality of locking pockets  
surrounding one of the plurality of vessel openings.

20 27. The apparatus of claim 26, wherein each locking pocket is substantially  
square.

28. The apparatus of claim 25, wherein each locking port comprises a locking  
opening and an O-ring surrounding the locking opening, and wherein the locking  
opening is connected to a vacuum line for drawing a partial vacuum in the locking  
25 opening.

29. The apparatus of claim 28, wherein the vacuum line is situated internal to the  
locking arm.

30. The apparatus of claim 23, wherein the locking arm support further comprises a drain trough for receiving waste material from a vessel situated in the locking arm when the locking arm is rotated to pour material from a vessel.

5 31. The apparatus of claim 30, wherein the drain trough includes a drain for draining waste fluid.

32. The apparatus of claim 23, wherein the drive mechanism comprises:  
a motor having a drive shaft, the motor connectable to an external motor  
10 control;  
a drive gear operatively coupled to the drive shaft;  
a free gear operatively, fixedly coupled to the rotatable locking arm; and  
a belt seated over the drive gear and the free gear, and wherein the belt is  
movable to drive the free gear in response to motion of the drive gear.

15 33. The apparatus of claim 32, wherein each of the drive gear and the free gear has a plurality of gear notches, and wherein the belt has a plurality of belt notches, the belt notches and gear notches matching in size.

20 34. The apparatus of claim 23, and further comprising a registration mechanism, the registration mechanism comprising:  
a registration disk operatively, fixedly coupled to the free gear, the  
registration disk having a registration slot therein;  
an optocoupler having a transmitter and a receiver separated by a gap,  
25 wherein the registration disk is positioned to extend into the gap; and  
control lines operatively electrically connected to the optocoupler and to the  
motor; and  
wherein the registration slot is aligned in the gap of the optocoupler when the  
registration disk is in a home position wherein the locking arm is in a  
30 substantially vertical position.

35. The apparatus of claim 34, wherein the motor queries the receiver, and drives the drive shaft to rotate the registration disk to its home position.

36. The apparatus of claim 24, wherein the motor further comprises a processor  
5 and a memory, the memory capable of storing a plurality of operating commands for the motor, and the processor capable of executing the stored commands to operate the motor.

37. The apparatus of claim 23, wherein the base includes a plurality of guide pin  
10 openings, the apparatus further comprising:

a supplemental cradle having a plurality of cradle vessel openings each sized  
to accomodate a vessel, the supplemental cradle having a plurality of  
guide pins extending therefore to engage the guide pins with the guide  
pin openings to position the supplemental cradle on the base.

15

38. The apparatus of claim 37, wherein the supplemental cradle further comprises a plurality of locking pockets, each of the locking pockets surrounding one of the plurality of vessel openeings.

20 39. The apparatus of claim 38, wherein each of the locking pockets is substantially square.

### Abstract of the Disclosure

A mixing and pouring apparatus for computer controlled processing of mixing and pouring operations includes a rotatable arm capable of holding vessels  
5 therein, the arm rotatable at programmable speeds and time lengths to perform automated moving and pouring processes. The present invention further provides a cap and vessel positioning system that securely locks a vessel in place and realigns the cap in essentially the identical position in relation to the vessel every time the vessel is capped. In one embodiment, both the cap and vessel have flanges that are  
10 aligned when the cap is properly secured to the vessel.

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15 "Express Mail" mailing label number *EL530190770VS*

Date of Deposit *October 20, 1999*

Printed name *Chris Hammond*

Signature *Chris Hammond*

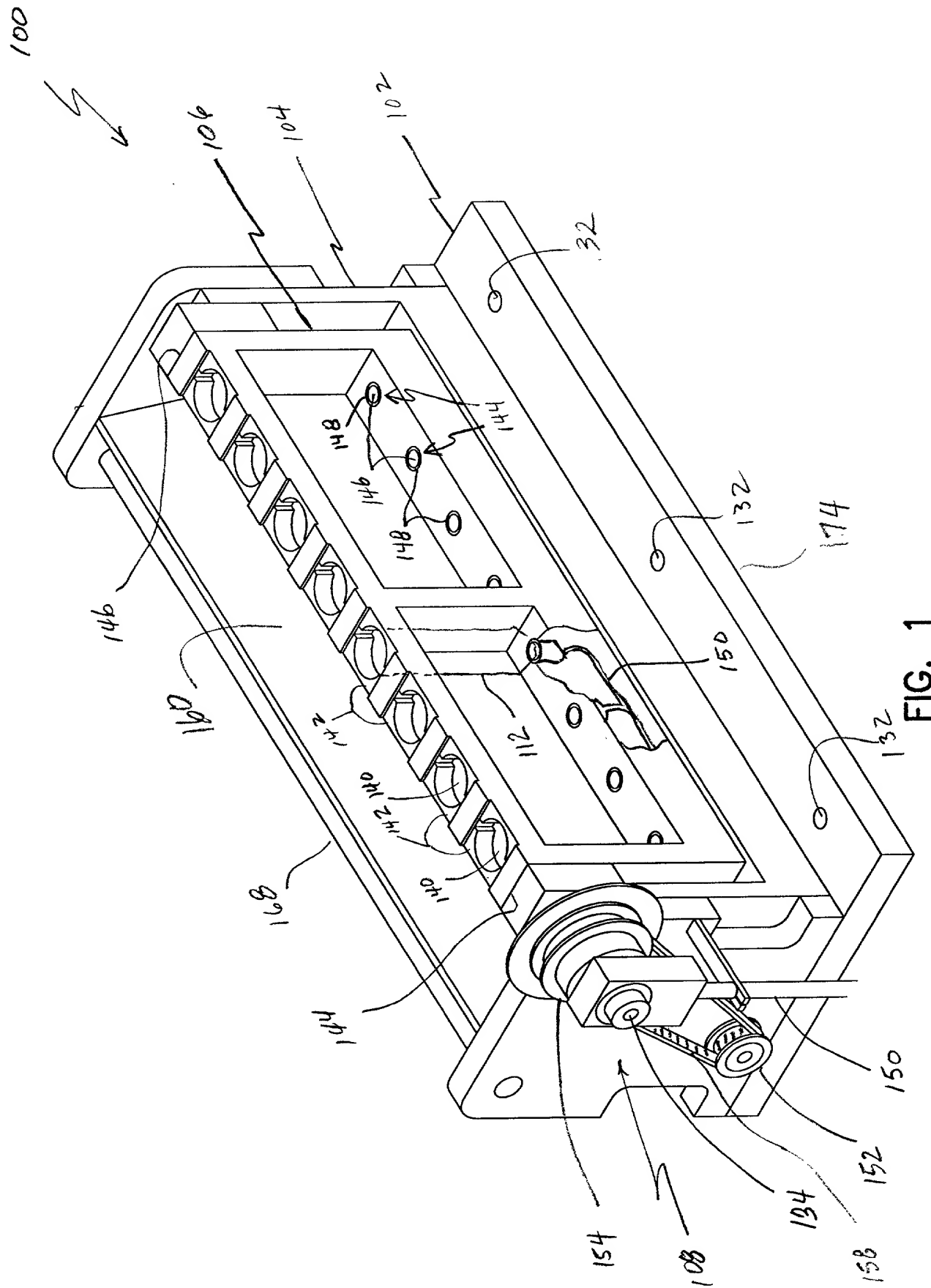


FIG. 1

FIG. 2

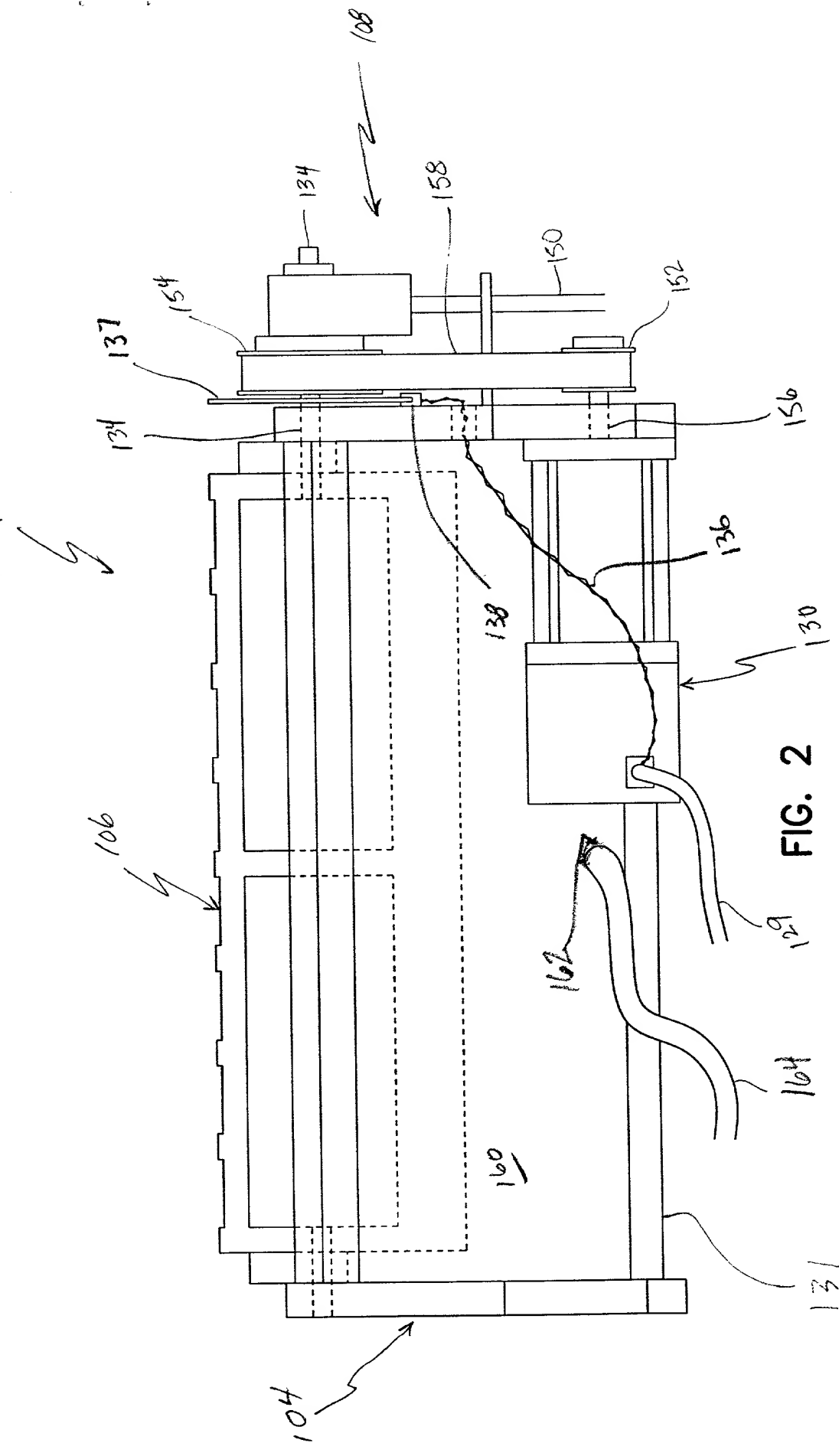


FIG. 2

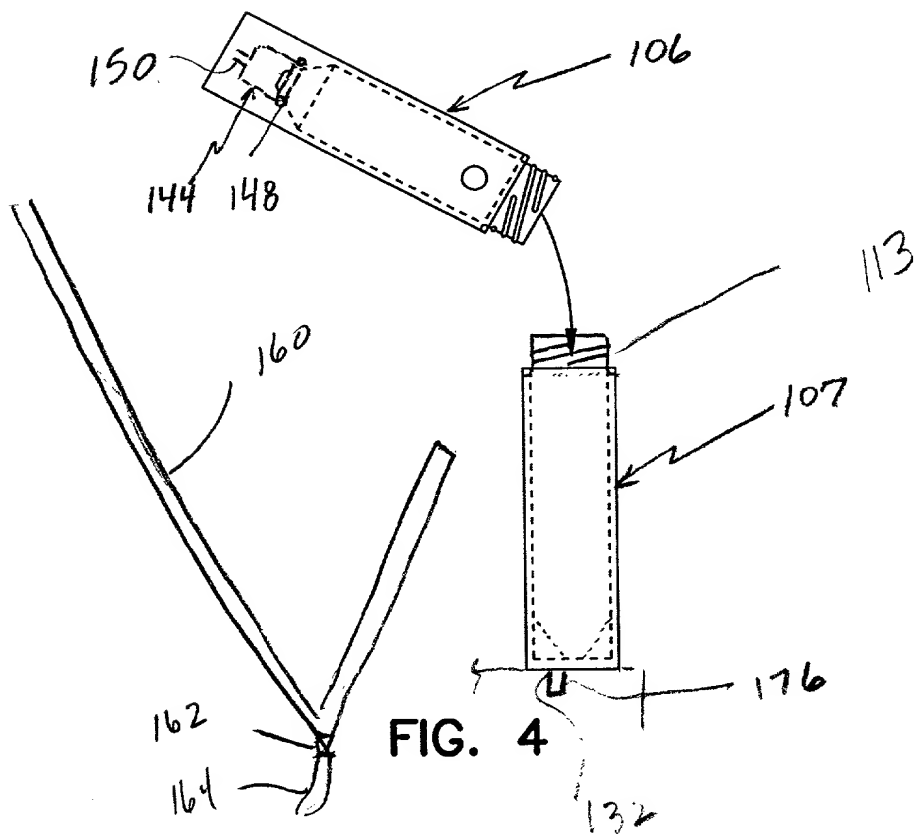
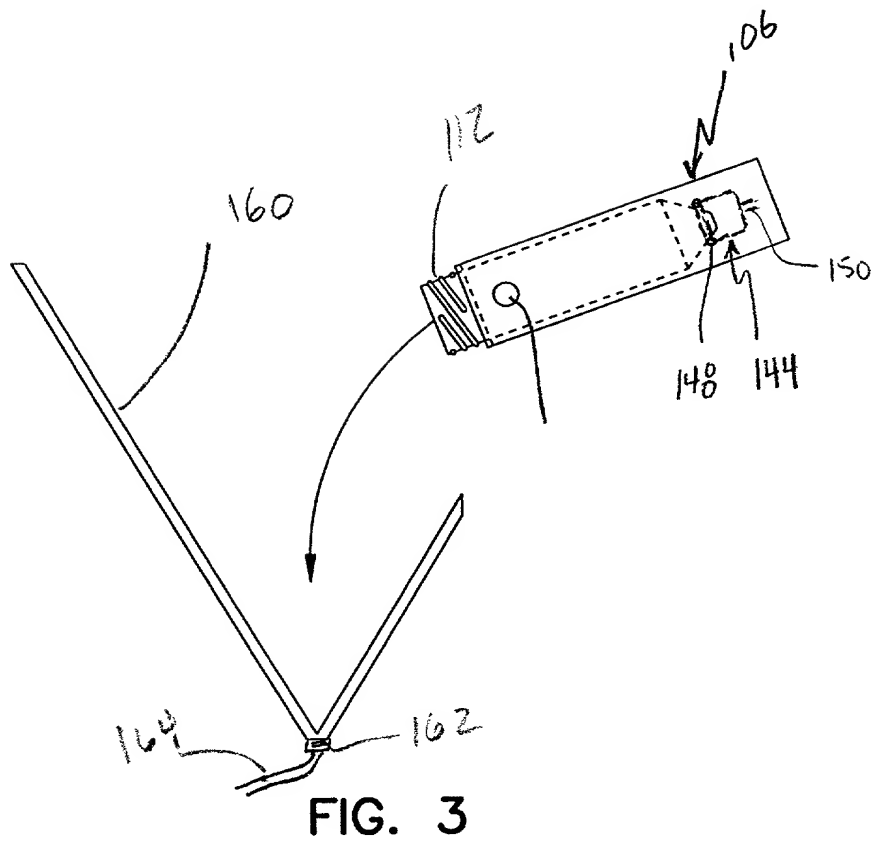




FIG. 5

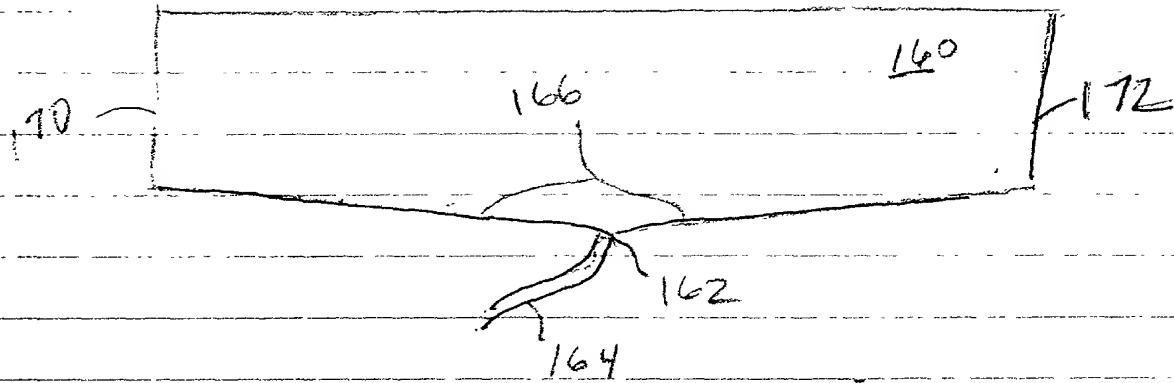


FIG. 6

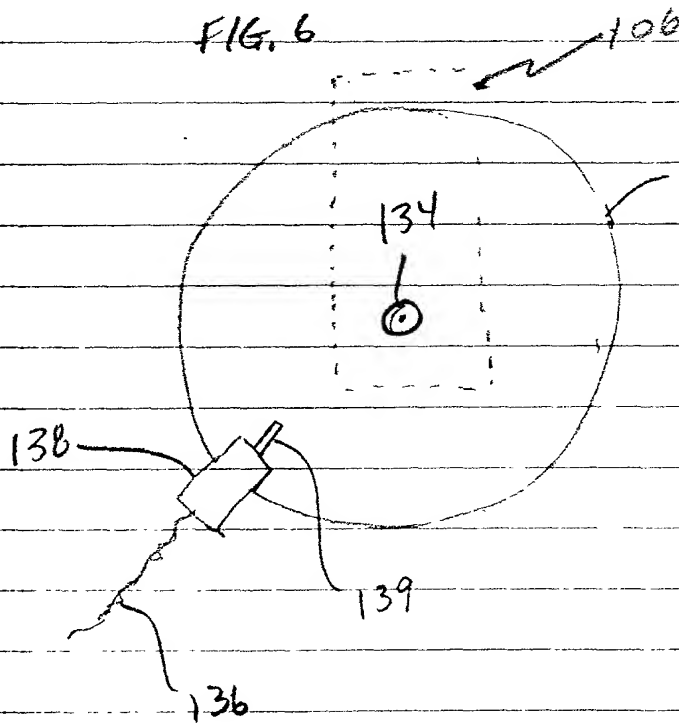


FIG. 7

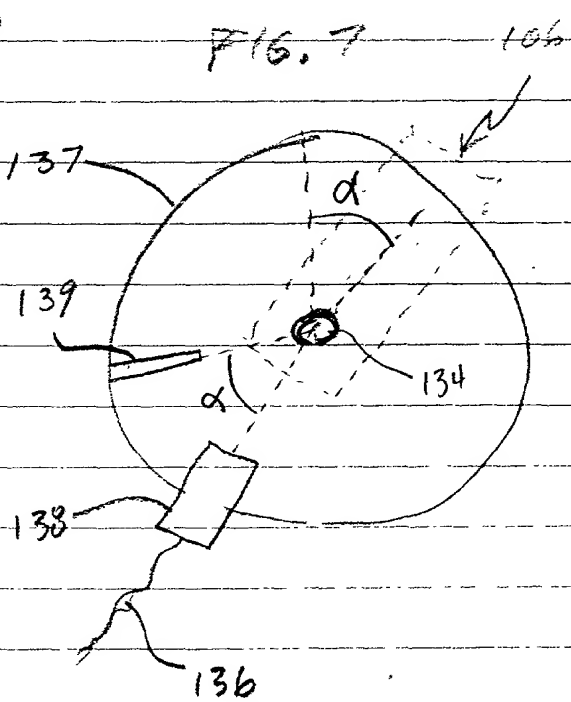


FIG. 8

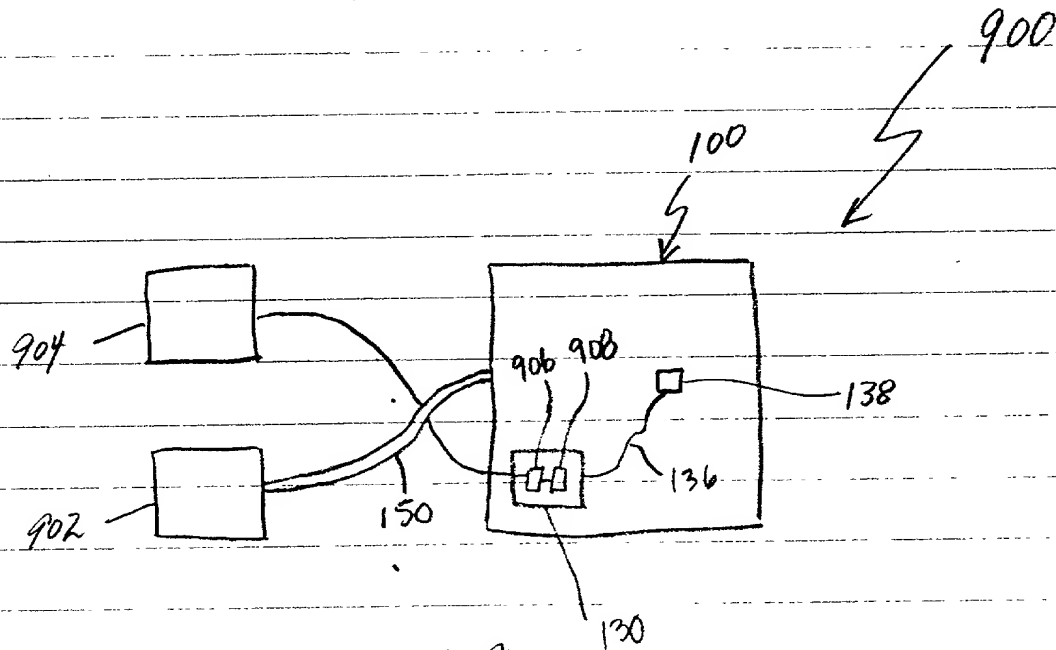
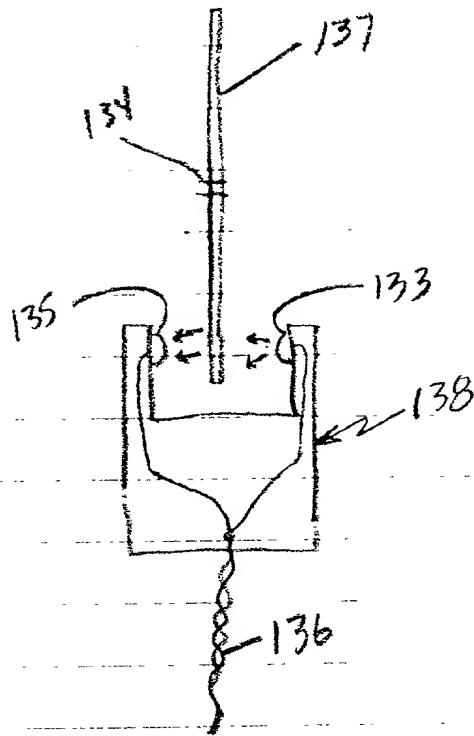
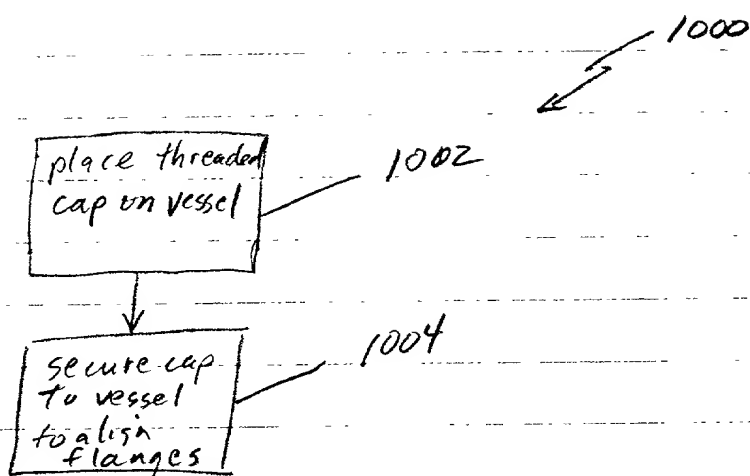


FIG. 9

FIG. 10



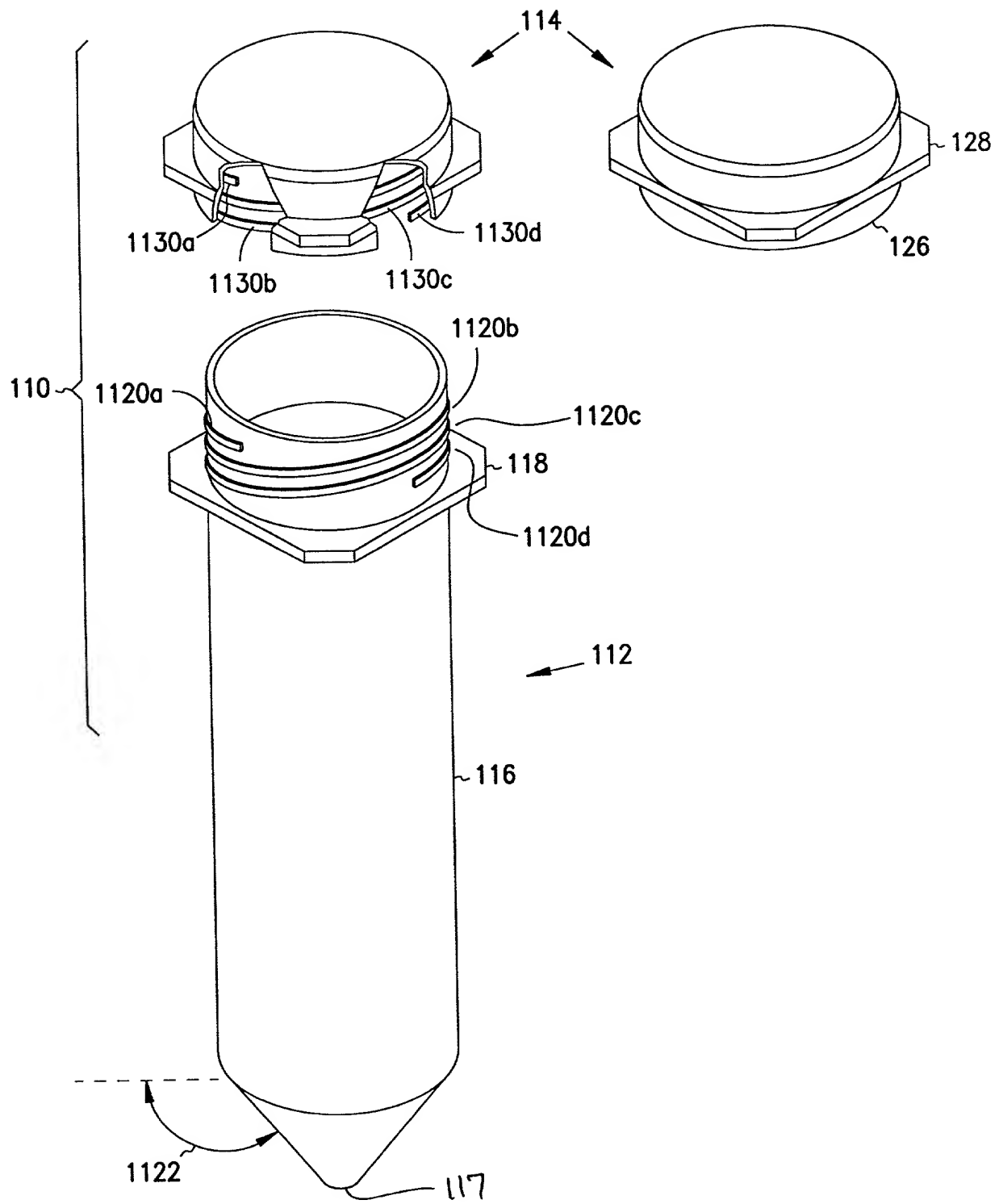


FIG. 11

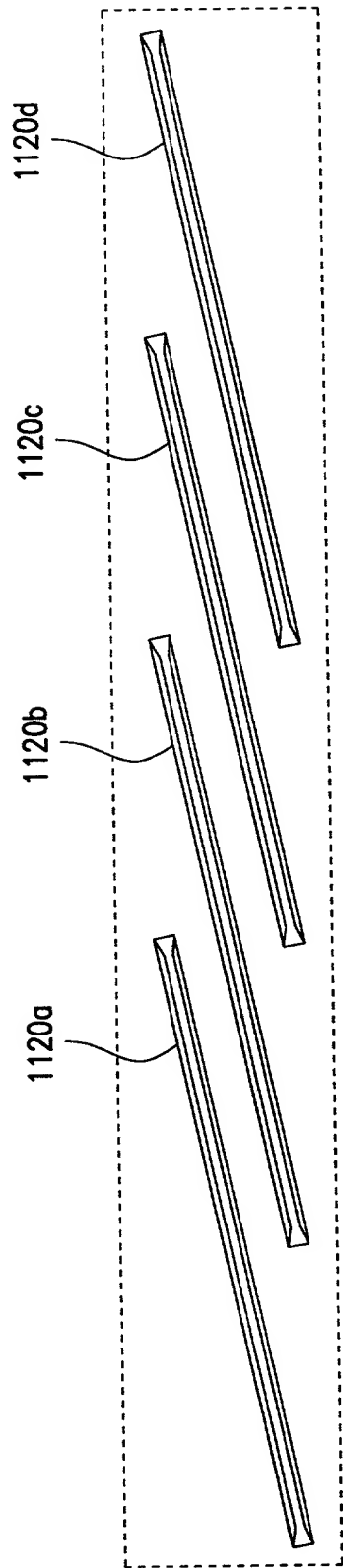


FIG. 11A

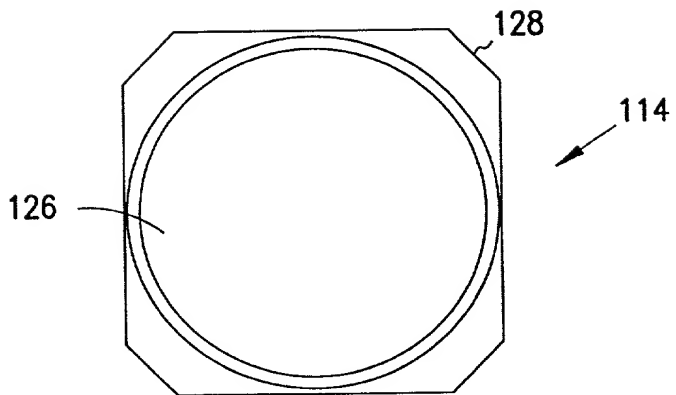


FIG. 12A

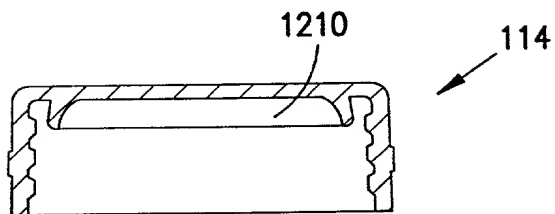


FIG. 12B

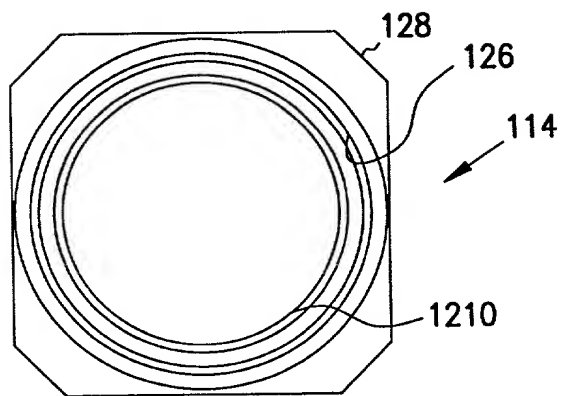


FIG. 12C

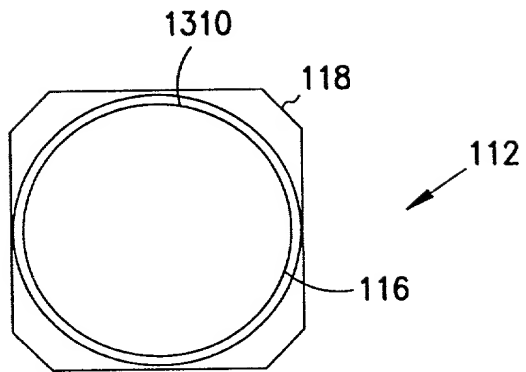


FIG. 13A

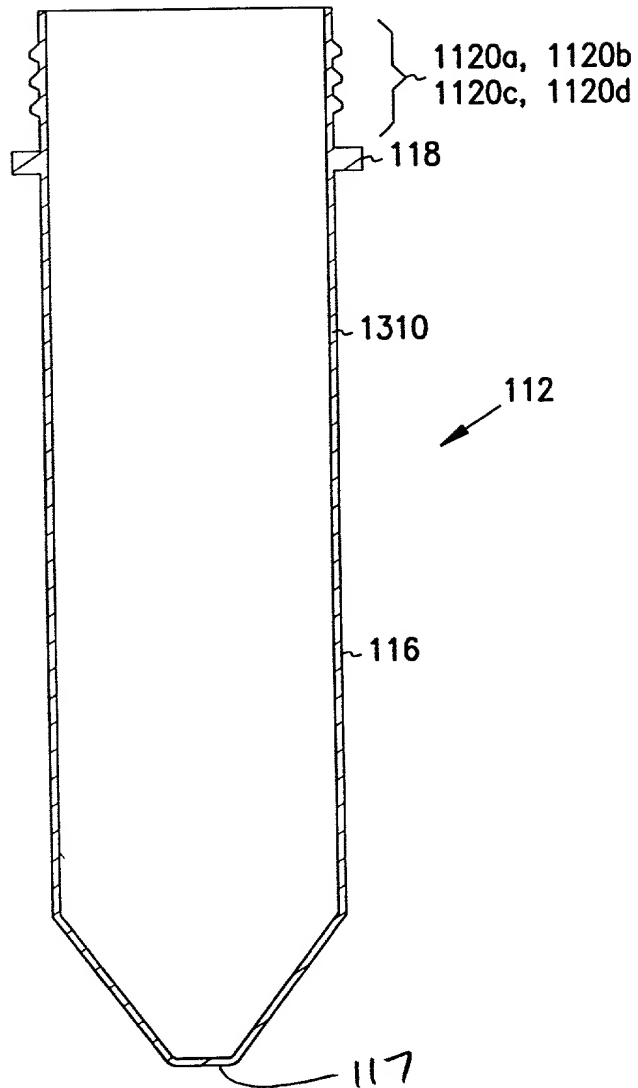


FIG. 13B

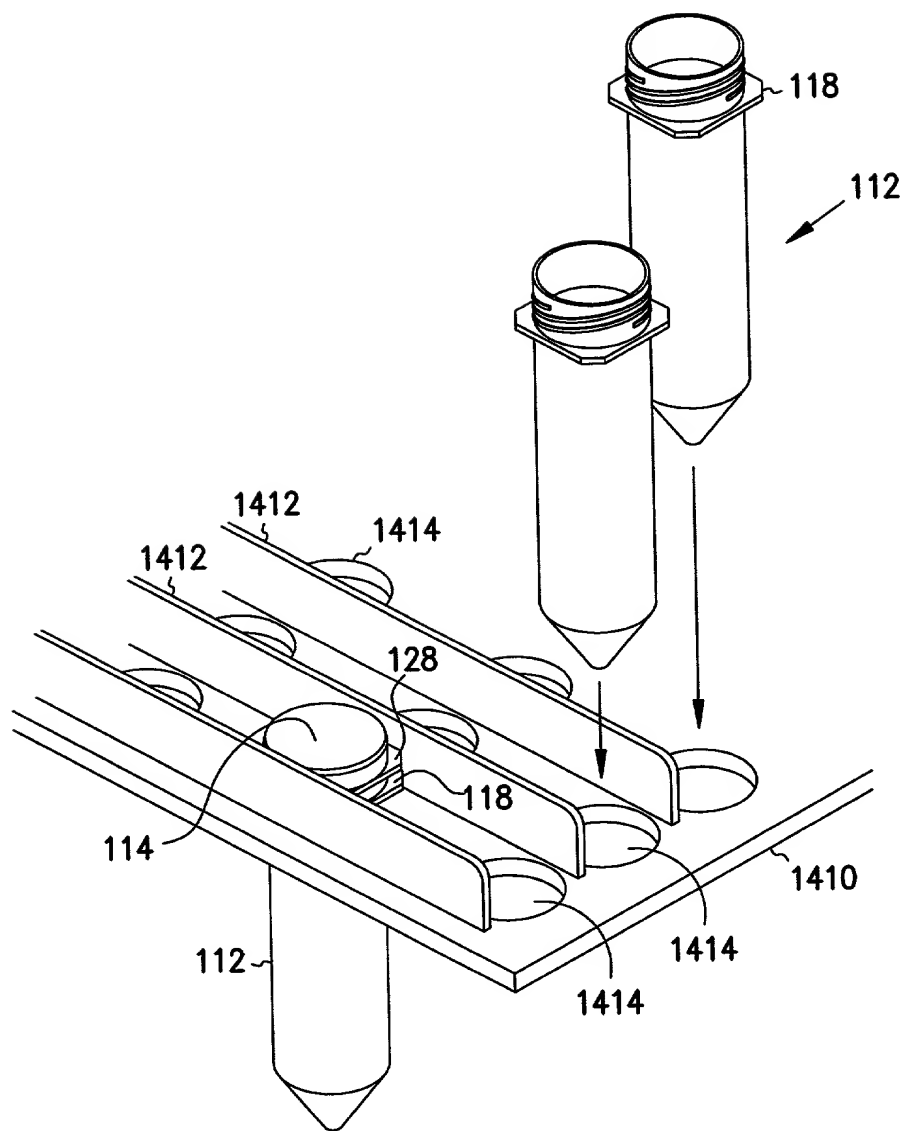


FIG. 14



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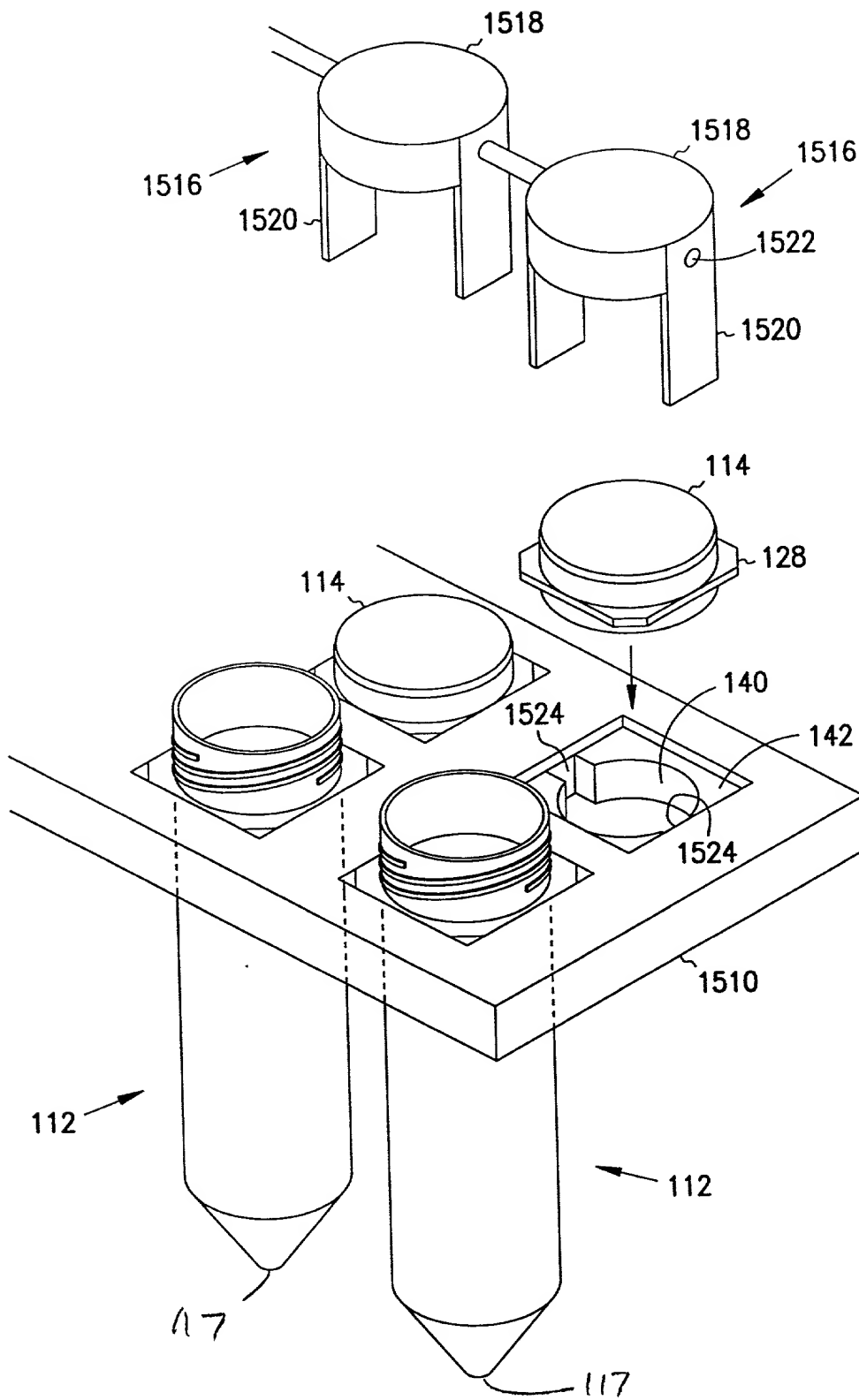


FIG. 15

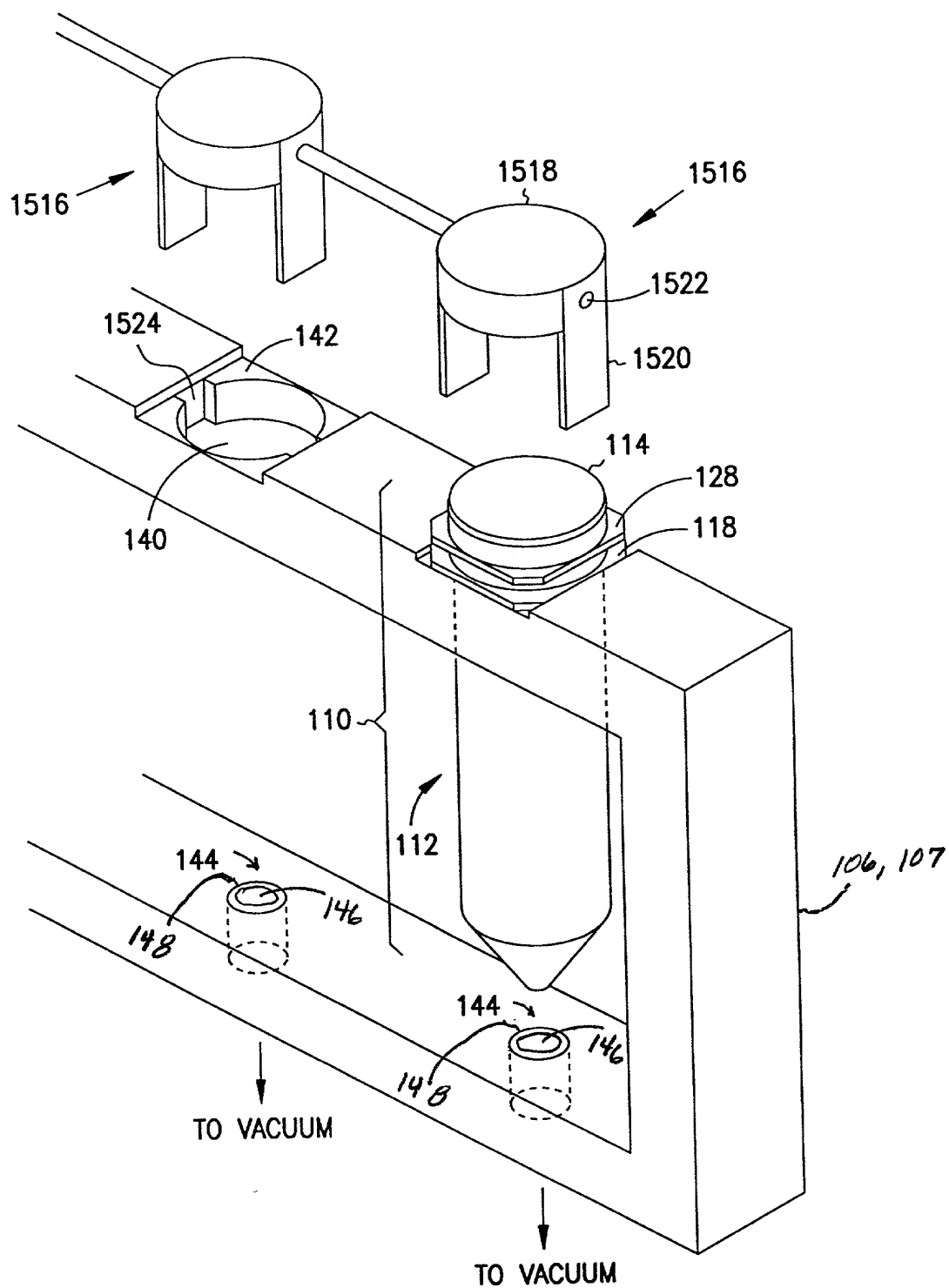


FIG. 16

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

# United States Patent Application

## COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **MIXING AND POURING APPARATUS AND VESSEL THEREFOR.**

The specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. § 1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with 37 C.F.R. § 1.63(e).

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

**No such claim for priority is being made at this time.**

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

**No such claim for priority is being made at this time.**

I hereby claim the benefit under 35 U.S.C. § 120 or 365(c) of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

**No such claim for priority is being made at this time.**

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

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Anglin, J. Michael	Reg. No. 24,916	Huebsch, Joseph C.	Reg. No. 42,673	Nielsen, Walter W.	Reg. No. 25,539
Arora, Suneel	Reg. No. 42,267	Jurkovich, Patti J.	Reg. No. 44,813	Oh, Allen J.	Reg. No. 42,047
Bianchi, Timothy E.	Reg. No. 39,610	Kalis, Janal M.	Reg. No. 37,650	Padys, Danny J.	Reg. No. 35,635
Billion, Richard E.	Reg. No. 32,836	Kaufmann, John D.	Reg. No. 24,017	Parker, J. Kevin	Reg. No. 33,024
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Brooks, Edward J., III	Reg. No. 40,925	Leffert, Thomas W.	Reg. No. 40,697	Prout, William F.	Reg. No. 33,995
Chu, Dinh C.P.	Reg. No. 41,676	Lemaire, Charles A.	Reg. No. 36,198	Schumm, Sherry W.	Reg. No. 39,422
Clark, Barbara J.	Reg. No. 38,107	Litman, Mark A.	Reg. No. 26,390	Schwegman, Micheal L.	Reg. No. 25,816
Dahl, John M.	Reg. No. P-44,639	Lundberg, Steven W.	Reg. No. 30,568	Sieffert, Kent J.	Reg. No. 41,312
Drake, Eduardo E.	Reg. No. 40,594	Mack, Lisa K.	Reg. No. 42,825	Slifer, Russell D.	Reg. No. 39,838
Eliseeva, Maria M.	Reg. No. 43,328	Maki, Peter C.	Reg. No. 42,832	Smith, Michael G.	Reg. No. P-45,368
Embreton, Janet E.	Reg. No. 39,665	Malen, Peter L.	Reg. No. 44,894	Steffey, Charles E.	Reg. No. 25,179
Fogg, David N.	Reg. No. 35,138	Mates, Robert E.	Reg. No. 35,271	Terry, Kathleen R.	Reg. No. 31,884
Fordenbacher, Paul J.	Reg. No. 42,546	McCrackin, Ann M.	Reg. No. 42,858	Viksins, Ann S.	Reg. No. 37,748
Forrest, Bradley A.	Reg. No. 30,837	Nama, Kash	Reg. No. 44,255	Woessner, Warren D.	Reg. No. 30,440

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Please direct all correspondence in this case to **Schwegman, Lundberg, Woessner & Kluth, P.A.** at the address indicated below:  
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**Telephone No. (612)373-6900**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Ellen M. Heath

Date: \_\_\_\_\_

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Signature: \_\_\_\_\_  
Ruth Shuman

Date: \_\_\_\_\_

☒ Additional inventors are being named on separately numbered sheets, attached hereto.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Douglas J. Kluge

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§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
  - (i) Opposing an argument of unpatentability relied on by the Office, or
  - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.